c.) Remarks

Claims 31-33 have been amended in order to recite the present invention with the specificity required by statute. The subject matter of the amendment may be found in the specification as filed, *inter alia*, at page 27, lines 2-33. Accordingly, no new matter has been added.

The May 4, 2004 Office Action restricted the claims improperly based on U.S. restriction practice. Accordingly, while the Examiner has not reformulated the restriction requirement in the present Office Action, the Examiner too has not made the requirement "final" in order to afford an opportunity to traverse the reasons now given for lack of unity. This courtesy is gratefully acknowledged. Nonetheless, solely in order to reduce the issues and expedite prosecution herein, the withdrawn claims have been cancelled without prejudice.

The Examiner has objected to the title and claims 32-33 for the formal reasons noted. In response, the title and claims 32-33 have been amended in conformity with the Examiner's kind suggestions.

Claims 31-33 and 38 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In response, claims 31 and 33 have been amended in conformity with the Examiner's suggestions as well.

Additionally, the Examiner states the specification teaches only a few representative species of β1,3-N-acetylglucosaminyltransferases and β1,4-galactosyltransferases. Because no other species are disclosed, the Examiner states the specification does not adequately

describe the application. Claims 31-33 and 38 are also rejected under 35 U.S.C. §112, first paragraph, as failing to be supported on an enabling disclosure for these reasons.

In response, claims 31 and 33 have also been amended to recite that the polypeptide consists of SEQ ID NO:2, positions 45-372 of SEQ ID NO:2, or an amino acid sequence having 95% or more homology with the above and having ß1, 3-N-acetylglucosaminyltransferase activity. In this regard, DNA encoding a polypeptide consisting of an amino acid sequence having 95% or more homology with, SEQ ID NO:2 (or positions 45-372 thereof) is readily obtained, for example, by hybridization using chromosomal DNA or cDNA in accordance with the teachings of the specification from page 25, line 34 to page 26, line 15, and the polypeptide is readily obtained according to the methods described from specification page 32, line 6 to page 47, line 32.

Claims 31 and 38 are rejected under 35 U.S.C. §102(b) as anticipated by either of Sasaki (*PNAS* 94:14294-99) or Zhou (*PNAS* 96:406-11), and claims 31-33 and 38 as anticipated by Di Virgillio (*Glycobiology* 9(4):353-64). Additionally, claims 31 and 38 are rejected under 35 U.S.C. §102(e) as anticipated by Fukuda (WO 01/85177), and claims 32 and 33 are rejected under 35 U.S.C. §103(a) as being obvious over DiVirgillio in view of Fukuda (WO 01/85177).

This rejection is respectfully traversed. However, prior to addressing this rejection, Applicants would first like to briefly discuss the salient features of the present invention and, *inter alia*, its patentable nature over the prior art.

As the Examiner will appreciate, claims 31 and 33 are, now, most broadly directed to methods of producing a sugar chain or complex carbohydrate using a polypeptide

consisting of an amino acid sequence having 95% or more homology with the amino acid sequence represented SEQ ID NO:2 (or amino acid positions 45-372 thereof).

In contrast, the ß1,3-N-acetylglucosaminyltransferases disclosed by Sasaki has only 27.8% homology with the amino acid sequence represented by SEQ ID NO:2 as shown in the sheet A attached at Tab A.

Similarly, the ß1,3-N-acetylglucosaminyltransferases disclosed by Zhou has only 17.5% homology with the amino acid sequence represented by SEQ ID NO:2, see specification page 79, lines 6 to 9.

However, Di Virgillio does not disclose any amino acid sequence of any ß1,3-N-acetylglucosaminyltransferases and does not provide a *prima facie* case of anticipation. *Elan Pharm. Inc. v. Mayo Foundation*, 68 USPQ2d 1373 (Fed. Cir. 2003), citing *PPG Industries, Inc. v. Guardian Industries Corp.*, 37 USPQ2d 1618, 1624 (Fed. Cir. 1996).

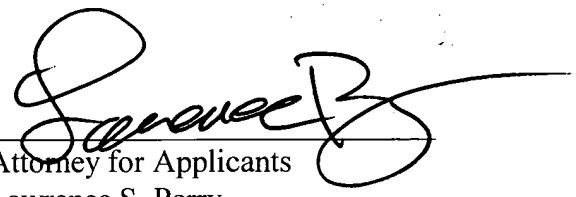
Finally, Fukuda discloses ß1,3-N-acetylglucosaminyltransferases that are identical to SEQ ID NO:2. However, Fukuda's earliest effective U.S. filing date (May 11, 2000) follows Applicants' March 16, 2000 Japanese priority date. Applicants have, accordingly, prepared and enclose a verified English translation of the Japanese priority application No. 2000-74757. For that reason, Fukuda is no longer available as prior art herein.

In view of the above amendments and remarks, Applicants submit that all of the Examiner's concerns are now overcome and the claims are now in allowable condition. Accordingly, reconsideration and allowance of this application is earnestly solicited.

Claims 31-33 and 38 remain presented for continued prosecution.

Applicants' undersigned attorney may be reached in our New York office by telephone at (212) 218-2100. All correspondence should continue to be directed to our below listed address.

Respectfully submitted,



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LSP\ac

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Sheet A

KYOWA

Identity: 66/418 (15.8%)
Homology: 116/418 (27.8%)
Gaps: 49/418 (11.7%)
#=====================================

```
                      10            20        30        40
SEQ ID NO:2    MKY-LRHRRPNATLILA----IGAFTLLLFSLLVSPPTCKVQEQP----P
               :.     :     :.::    .. . :: .::: .    . :.:     :
Sasaki et al.  MQMSYAIRCAFYQLLLAALMLVAMLQLLYLSLLSGLHGQEEQDQYFEFFP
                      10        20        30        40        50

          50        60            70        80
       AIPEALAWPTPPTRPAPAP---CHANTSMVTHPDFATQPQHVQNFLLYRH
         :...       : : :      :. .  ..  .    .  .. .:  :
       PSPRSVDQVKAQLRTALASGGVLDASGDYRVYRGLLKTTMDPNDVILATH
          60        70        80        90        100

       90            100       110       120       130
       CR-----HFPLLQDVPPSKCAQPVFLLLVIKSSPSNYVRRELLRRTWGRE
       .      :.  : .   .  .  ::     ... .. .   : .    .
       ASVDNLLHLSGLLERWEGPLSVSVFAATKEEAQLATVLAYALSSHCPDMR
          110       120       130       140       150

      140       150       160          170       180
       RKVRGLQLRLLFLVGTASNPHEARKVNRLLELEA--QTHGDILQWDFHDS
        .:    .      ... .:.:  .   : . .   .  . . : .. .
       ARVAMHLVCPSRYEAAVPDPREPGEFALLRSCQEVFDKLARVAQPGINYA
          160       170       180       190       200

         190       200       210           220
       FFNLTLKQVLFLQWQETRCANASFVLNGD----DDVFAHTDNMVFYLQDH
       . . .     .:.    . :: ..:.. :    . ..    .:.   :..
       LGTNVSYPNNLLRNLAREGANYALVIDVDMVPSEGLWRGLREMLD--QSN
          210       220       230       240
```

KYOWA

```
230        240        250        260             270
DPGRHLFVGQLIQNVGPIRAFWSKYYVPEVVTQNERYPPYCG-----GGG
. :   .:   ..      :   .: . ..   .:  : : :      .
QWGGTALVVPAFEIRRARRMPMNKNELVQLYQVGEVRPFYYGLCTPCQAP
250        260        270        280        290

     280        290        300        310        320
FLLSRFTAAALRRAAHVLDIFPIDDVFLGMCLELEGLKPASHSGIRTSGV
   ::..    .   .   . : .: .  . .   :  :.  . .:  :
TNYSRWVNLPEESLLRPAYVVPWQDPWEPFYVA-GGKVPTFDERFRQYGF
300        310        320        330        340

          330        340        350         360
RAPSQ----HLSSFDPCFYRDLLLVHRFLPYEMLL--MWDALNQPNLTC-
.  ::    :...::    .. .:::. .   . .  . .: :: :
NRISQACELHVAGFDFEVLNEGFLVHKGFKEALKFHPQKEAENQHNKILY
350        360        370        380        390

             370
-----------GNQTQIY
            :. .
RQFKQELKAKYPNSPRRC
400        410
```